December 18, 2018

Apex Biotechnology Corp.
Lisa Liu
Manager of Quality Assurance Division
No. 7, Li-Hsin Road V, Hsinchu Science Park
Hsinchu, 30078
Taiwan

Re: K182593
Trade/Device Name: KET-1 Blood Ketone Monitoring System
Regulation Number: 21 CFR 862.1435
Regulation Name: Ketones (nonquantitative) test system
Regulatory Class: Class I, meets the limitation of exemption 21 CFR 862.9(c)(5)
Product Code: JIN
Dated: September 13, 2018
Received: September 20, 2018

Dear Lisa Liu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or post marketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182593

Device Name
KET-1 Blood Ketone Monitoring System

Indications for Use *(Describe)*
The KET-1 Blood Ketone Monitoring System is intended to quantitatively measure β-hydroxybutyrate (β-ketone) in fresh capillary whole blood from fingertips. It should only be used by a single patient and it should not be shared. Testing is done outside the body (In Vitro diagnostic use). It is intended for self-testing by people with diabetes at home as an aid to monitoring the effectiveness of diabetes control programs. It is not to be used for diagnosis or screening of diabetes, or for neonatal use.
The KET-1 Blood Ketone Monitoring System is comprised of the KET-1 Blood Ketone Meter and KET-1 Blood Ketone Test Strip.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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9 510(k) Summary

510(k) number	K182593
Submitter:	Apex Biotechnology Corp. No. 7, Li-Hsin Road V, Hsinchu Science Park Hsinchu, 30078 CHINA (TAIWAN)
Contact Person:	Lisa Liu Manager of Quality Assurance Division Apex Biotechnology Corp. No. 7, Li-Hsin Road V, Hsinchu Science Park Hsinchu, 30078 CHINA (TAIWAN) email: lisaliu@apexbio.com Phone: 011-886-3-5641952 FAX: 011-886-3-5678021
Date Prepared:	December 05, 2018
Trade Names:	KET-1 Blood Ketone Monitoring System
Classification:	Ketones (nonquantitative) test system, 21 CFR 862.1435, Class I, meets limitation of exemptions 21 CFR 862.9(c)(5)
Product Codes:	JIN
Predicate Devices:	Nova Max Plus Blood Glucose and β-ketone Monitor System (k091547)
Device Description:	The KET-1 Blood Ketone Monitoring System consists of the KET-1 Blood Ketone Meter, KET-1 Blood Ketone Test Strips, and KET-1 Ketone Control Solutions (Level 1 and Level 2). The system is for self-testing of blood ketone. The KET-1 Blood Ketone Test Strips and KET-1 Ketone Control Solutions are purchased separately.

Intended Use:	KET-1 System: The KET-1 Blood Ketone Monitoring System is intended to quantitatively measure β-hydroxybutyrate (β-ketone) in fresh capillary whole blood from fingertips. It should only be used by a single patient and it should not be shared. Testing is done outside the body (In Vitro diagnostic use). It is intended for self-testing by people with diabetes at home as an aid to monitoring the effectiveness of diabetes control programs. It is not to be used for diagnosis or screening of diabetes, or for neonatal use. The KET-1 Blood Ketone Monitoring System is comprised of the KET-1 Blood Ketone Meter and KET-1 Blood Ketone Test Strip.
Comparison of Technological Characteristics:	The β-ketone (ß-Hydroxybutyrate) measurement is based on amperometric biosensor technology using the enzyme β-hydroxybutyrate dehydrogenase. The enzyme reacts with ß-Hydroxybutyrate in blood and produces electrical current that the magnitude of electrical current resulting from this enzymatic reaction is proportional to the amount of β-hydroxybutyrate. The meter measures the electrical current and displays the concentration of ß-Hydroxybutyrate in blood. The technological characteristics of KET-1 Blood Ketone Monitoring System are substantially equivalent to the predicate system (k091547).
Non-Clinical Testing:	Testing was conducted as follows: EMC and Electrical Safety, disinfection performance (robustness of meter to multiple cleanings and disinfections), software verification and validation, linearity testing with validation of Lo/Hi detection, temperature and humidity testing, sample volume verification, precision testing, repeatability testing, interferences testing, altitude testing, qualification of control solutions, hematocrit performance testing, results demonstrate substantial equivalence to the predicate system.
Clinical Testing	An accuracy study was conducted with home users using finger capillary whole blood. Results demonstrate substantial equivalence to the predicate system.
Conclusion:	Clinical and non-clinical testing demonstrated that the KET-1 Blood Ketone Monitoring Systems perform in a substantially equivalent manner to that of the predicate. We conclude that the KET-1 Blood Ketone Monitoring Systems is substantially equivalent to the predicate system.